UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

LAKE CHARLES DIVISION

WILBERT MALBROUX,JR.	:	**DOCKET NO. 11-421**
VS.	:	**JUDGE TRIMBLE**
DR. J.J.JANCUSKA AND AMERICAN MEDICAL SYSTEMS	:	**MAGISTRATE JUDGE KAY**

MEMORANDUM RULING

Before the court is "American Medical Systems' Motion to Dismiss" (R. #10) wherein the defendants seek to dismiss the instant lawsuit because the plaintiff's claims are (1) preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA")[1], and/or (2) the petition fails to allege facts sufficient to fairly place defendant on notice as to the nature of the claims being asserted.[2]

FACTUAL ALLEGATIONS

Plaintiff had an Inflatable Penile Prosthesis[3] installed on May 7, 2007. Plaintiff alleges that the procedure was not successful; he is representing himself in a *pro se* capacity. Plaintiff alleges that the device is defective because it never worked properly.[4] Plaintiff complains (1) that he has

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[1] 21 U.S.C. § 360k(a); Riefel v. Medtronic, Inc., 552 U.S.312, 128 S.Ct. 999 (2008).

[2] Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S.Ct. 1955 (2007); Ashcroft v. Iqbal, – U.S. – ,129 S.Ct. 1937 (2009).

[3] AMS 700 Series Inflatable Penile Prosthesis; this device is used in the treatment of chronic, organic, male erectile dysfunction.

[4] R. #1, ¶ 2.

not been able to interact with the opposite sex for three years, (2) that he has suffered physical pain, (3) he has suffered loss of enjoyment of life, as well as (4) fear that public knowledge about his medical inadequacies are made known. Plaintiff seeks to have corrective surgery by a doctor of his choosing and damages.

RULE 12(B)(6) STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows dismissal of a complaint when it fails to state a claim upon which relief can be granted. The test for determining the sufficiency of a complaint under Rule 12(b)(6) is that " 'a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.' "[5] Subsumed within the rigorous standard of the *Conley* test is the requirement that the plaintiff's complaint be stated with enough clarity to enable a court or an opposing party to determine whether a claim is sufficiently alleged.[6] The plaintiff's complaint is to be construed in a light most favorable to plaintiff, and the allegations contained therein are to be taken as true.[7] In other words, a motion to dismiss an action for failure to state a claim "admits the facts alleged in the complaint, but challenges plaintiff's rights to relief based upon those facts.[8] "In order to avoid dismissal for failure to state a claim, a plaintiff must plead specific facts, not mere

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[5] Hitt v. City of Pasadena, 561 F.2d 606,608 (5th Cir. 1977)(per curium) citing Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, (1957)).

[6] Elliot v. Foufas, 867 F.2d 877, 880 (5th Cir. 1989).

[7] Oppenheimer v. Prudential Securities, Inc., 94 F.3d 189, 194 (5th Cir. 1996).

[8] Tel-Phonic Servs., Inc. v. TBS Int'l, Inc., 975 F.2d 1134, 1137 (5th Cir. 1992).

conclusory allegations. . . ."[9] "Legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss."[10] "[T]he complaint must contain either direct allegations on every material point necessary to sustain a recovery . . . or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial."[11]

Under Rule 8 of the Federal Rules of Civil Procedure, the pleading standard does not require a complaint to contain "detailed factual allegations," but it demands "more than an unadorned, the defendant-unlawfully-harmed-me accusation."[12] A complaint that offers "labels and conclusions:" or "a formulaic recitation of the elements of a cause of action will not do."[13] Nor does a complaint suffice if it tenders "naked assertion[s]" devoid of "further factual enhancement."[14]

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face."[15]

LAW AND ANALYSIS

Preemption by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act

Defendant, American Medical Systems, Inc. ("AMS") maintains that plaintiff's claims are preempted by federal law rendering invalid any state tort law causes of action. Federal law

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[9] Guidry v. Bank of LaPlace, 954 F.2d 278, 281 (5th Cir. 1992).

[10] Blackburn v. City of Marshall, 42 F.3d 925, 931 (5th Cir. 1995).

[11] Campbell v. City of San Antonio, 43 F.3d 973, 975 (5th Cir. 1995).

[12] Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955 (2007).

[13] Id.

[14] Id., at 557, 127 S.Ct. 1955.

[15] Id.

categorizes medical devices into three groups: Class I, Class II, and Class III.[16] The Penile Prosthesis is a Class III medical device which is subject to the highest degree of oversight. Before a Class III medical device can be sold, it must receive an approval or clearance from the FDA.

The Medical Device Amendments ("MDA") contain an express preemption clause which renders invalid any state law that might result in the imposition of any device requirement that is "different from, or in addition to, any requirement applicable under this chapter."[17] This preemption clause operates to safeguard the Food and Drug Administration's ("FDA") comprehensive analysis concerning both PMA(Premarket Approval process)-approved and PDP(Product Development Protocol process)-completed devices from modification or interference through the varying tort law principles of the fifty states.[18] In Riegel, supra, the Supreme Court found that state-law claims of strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, sale, and manufacture were all preempted by Section 360k of the MDA because the device at issue (a Penile Prosthesis) was a PMA-approved, Class III medical device.[19]

The Riegel court employed a two-pronged analysis that considers (1) whether the FDA has established federal requirements that apply to the device in question, and (2) whether the asserted tort claims are based on state-law requirements "that are 'different from, or in addition to' the federal

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[16] 21 U.S.C. § 360c(a).

[17] 21 U.S.C. § 360k(a).

[18] See Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S.Ct. 999 (2008)(state law claims relating to Class III, PMA-approved devices that impose requirements different from or in addition to those of the FDA are to be preempted).

[19] Id., at 1005-1006, 1011.

ones and that related to safety and effectiveness."[20] AMS maintains that both prongs are satisfied.

In Riegel, the Supreme Court also found that the PMA process itself imposes device-specific, federal "requirements" for purposes of preemption analysis.[21] The Supreme Court noted that the PMA process is "specific to individual devices" because "the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness."[22] PDP completion is equivalent to PMA approval, thus, if a device is PMA-approved or has received a declaration of PDP completion, then the first prong of the preemption analysis is satisfied.

On November 2, 1998, the Penile Prosthesis that is the subject of this lawsuit received a declaration of PDP completion.[23] The conditions of PDP approval governs AMS's design, manufacturing and labeling of the device. Therefore, through the PDP process, the FDA has established federal "requirements" that apply specifically to the Penile Prosthesis. Hence, the first prong of the Riegel preemption analysis is satisfied.

AMS maintains that plaintiff's allegations are different from, or in addition to the federal requirements related to safety and effectiveness.[24] In his complaint, plaintiff alleges that the Penile Prosthesis is defective, meaning that it is not reasonably safe and effective as designed, manufactured and labeled. This assertion is directly contrary to the FDA's declaration of PDP completion, which

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[20] Id. at 1006-1008.

[21] Id. at 1006-1007.

[22] Id. at 1007.

[23] AMS exhibit 2– FDA Declaration of PDP Completion. The Court is entitled to take judicial notice of this fact because it is reflected in the public records of the FDA.

[24] Riegel, 128 S.Ct. at 1006-1008.

is premised upon a finding by the FDA that the Penile Prosthesis is, in fact, reasonably safe, effective and appropriately labeled.[25] In Cowen v. American Medical Systems, Inc.[26] with respect to a Penile Prosthesis being alleged as defective, the court concluded that "[t]o permit a jury verdict in favor of Plaintiff for a design defect would impliedly require more of Defendant than what the FDA already required." Accordingly, such requirements would be "different from" or "in addition to" those set forth by the FDA and as such, is in violation of § 360k(a). Accordingly, we find that any potential claims that plaintiff is attempting to assert in his complaint are preempted by federal law and must be dismissed.

CONCLUSION

For the reasons set forth above, the motion to dismiss will be granted dismissing with prejudice, plaintiffs' claims because they are preempted by federal law.

THUS DONE AND SIGNED in Chambers at Lake Charles, Louisiana, this 29th day of August, 2011.

JAMES T. TRIMBLE, JR.
UNITED STATES DISTRICT JUDGE

[25] See Cowan, supra, 2006 WL 3542704, at *2.

[26] Id..